General

Guideline Title

Patient blood management guidelines: module 5 - obstetrics and maternity.

Bibliographic Source(s)

National Blood Authority. Patient blood management guidelines: module 5 - obstetrics and maternity. Canberra ACT (Australia): National Blood Authority; 2015. 129 p. [134 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the levels of evidence (I, II, III-1, III-2, III-3, IV) and grades of recommendations (A-D, Practice Point) are provided at the end of the "Major Recommendations" field. The Clinical/Consumer Reference Group (CRG) also developed Expert Opinion Points related to the material covered in the background questions.

Oral and/or Parenteral Iron

The routine administration of iron supplementation to all pregnant women is not recommended[a] (Grade C).

The administration of iron to pregnant women with iron deficiency anaemia is recommended; intravenous (IV) iron is preferred when rapid restoration of haemoglobin (Hb) and iron stores is required (Grade C).

In maternity patients who require iron therapy for the treatment of anaemia, the routine addition of folic acid is not recommended[b] (Grade C).

In maternity patients with iron deficiency anaemia, a therapeutic dose of elemental iron (100–200 mg daily) should be prescribed, and the response to therapy monitored. If the response to oral iron is inadequate, IV iron should be used (Practice Point).

In maternity patients with iron deficiency without anaemia, a low dose of elemental iron (e.g., 20–80 mg daily) may be considered, and may be better tolerated than higher doses (Practice Point).

In maternity patients requiring iron, IV iron is preferred when oral iron is poorly tolerated (affecting compliance), or absorption is likely to be impaired (Practice Point).

When IV iron is prescribed, calculation of the dose should take into consideration the iron deficit (Practice Point).

The routine use of intramuscular (IM) iron is not advised where alternatives are available (Practice Point).

[a]In accordance with Clinical practice guidelines: Antenatal care – Module 1

[b]Folic acid should be administered for the prevention of neural tube defects, in accordance with Clinical practice guidelines: Antenatal care – Module 1.

Erythropoiesis Stimulating Agents (ESAs)

ESAs should not be routinely used in maternity patients (Grade C).

In maternity patients with anaemia, where an ESA is used, it should be combined with iron therapy[a] (Practice Point).

[a]ESAs are currently registered with the Therapeutic Goods Administration (TGA) for anaemia therapy in patients with chronic renal disease, non-myeloid malignancies and those scheduled for elective surgery with an expected moderate blood loss.

Blood Group and Screen During Pregnancy

All women should be offered routine blood group and antibody testing during pregnancy, with follow-up testing for Rh D negative women and women with alloantibodies capable of causing haemolytic disease of the newborn (HDN). Women with antibodies associated with moderate and severe HDN (-D, -c, -K) should consult with a specialist obstetrician with relevant expertise[a] (Expert Opinion Point).

Women with clinically significant alloantibodies should have a blood group and antibody screen on admission, in labour or prior to vaginal or caesarean birth, to avoid potential delays in blood provision. Where complex antibodies or rare red cell phenotypes are identified, and provision of compatible blood may be difficult, the management plan should include timely access to specialist blood product support (Expert Opinion Point).

Decisions regarding blood group and antibody screen prior to vaginal or caesarean birth should include a risk assessment for peripartum haemorrhage, and the presence of any factors that may delay access to blood, should it be required. Such factors include the presence of red cell alloantibodies, and the local arrangements for provision of testing and blood products (Expert Opinion Point).

[a]In accordance with Guidelines for blood grouping & antibody screening in the antenatal & perinatal setting.

Anaemia

In women at high risk of anaemia, ferritin should be tested along with full blood count (FBC) early in pregnancy to assess iron stores and anaemia. Other factors contributing to anaemia, such as deficiencies in folic acid and vitamin B12, or hookworm, should be screened for in selected women (Expert Opinion Point).

Women should be provided with information and advice in relation to minimising anaemia, for example, by adequate spacing of pregnancies, consumption of a healthy diet and optimal management of any medical comorbidities (Expert Opinion Point).

When Transfusion Is Not an Option

In all maternity patients, it is good clinical practice to optimise Hb during the antenatal period, minimise blood loss during birth and, in the event of haemorrhage, secure haemostasis as a matter of urgency. This is vital in patients for whom transfusion is not an option (Expert Opinion Point).

To arrest significant and life-threatening haemorrhage, when transfusion is not an option, the definitive procedure to minimise ongoing blood loss is hysterectomy, which must be considered and acted upon early (Expert Opinion Point).

Early identification of women for whom transfusion is not an option is vital, to enable a comprehensive multidisciplinary plan to be developed and implemented (Expert Opinion Point).

Women Who Are Not Actively Bleeding

In maternity patients who are not actively bleeding, red blood cell (RBC) transfusion should not be dictated by a Hb concentration alone, but should also be based on assessment of the patient's clinical status (e.g., the risk of further haemorrhage). Most maternity patients are otherwise healthy and can generally tolerate moderate degrees of anaemia while medical therapies take effect (Practice Point).

In maternity patients who are not actively bleeding, non-transfusion therapies, including iron, should be considered as part of the treatment of anaemia ("Oral and/or Parenteral Iron" above) (Practice Point).

In maternity patients who are not actively bleeding, where transfusion is indicated, a single unit of RBC, followed by clinical reassessment to

determine the need for further transfusion, is appropriate. This reassessment will also guide the decision on whether to retest the Hb level (Practice Point).

In maternity patients, the risk of RBC alloimmunisation and potential clinical impact should be considered when balancing the risks and benefits of RBC transfusion (Practice Point).

Direct evidence of the efficacy of RBC transfusion for treatment of anaemia is not available in maternity patients. Evidence from other patient groups and CRG consensus suggests that, with a:

- Hb concentration >90 g/L, RBC transfusion is usually inappropriate.
- Hb concentration of 70–90 g/L, RBC transfusion is not associated with reduced mortality. The decision to transfuse patients (with a single unit followed by reassessment) should be based on the need to relieve clinical signs and symptoms of anaemia, the availability of other therapies for the treatment of anaemia, the expected timeframe to giving birth and the presence of risk factors for haemorrhage.
- Hb concentration <70 g/L, RBC transfusion may be associated with reduced mortality and may be appropriate. However, transfusion may not be required in well-compensated patients, or where other specific therapy is available. (Practice Points)

Blood Component Transfusion - Modified Blood Components (Cytomegalovirus [CMV] Seronegative and Phenotyped)

CMV safe blood products should be offered to all pregnant women, regardless of CMV status, when transfusion occurs in the antenatal setting in the context of an ongoing pregnancy. Preference is for CMV seronegative blood products, where available; however, life-saving transfusion should not be withheld if CMV seronegative products are not available (Expert Opinion Point).

Note: CMV "safe" means through leucodepletion or antibody testing of donor blood. Neither process excludes the possibility of transfusion-transmitted infection; rather, they both provide a significant risk reduction. It is unknown whether CMV seronegative blood products provide significant additional protection over routine leucodepletion.

Where possible, K negative RBC should be selected for transfusion for all females of child-bearing potential who are K negative or whose K antigen status is unknown (Expert Opinion Point).

Coagulopathic Patients at Risk of Bleeding

In general, a platelet count $\geq 50 \times 10^9$/L is considered acceptable for vaginal or caesarean birth; however, lower platelet counts may be tolerated (Practice Point).

In maternity patients with abnormal coagulation tests who are not bleeding (note: concealed bleeding should be excluded), the routine use of cryoprecipitate or fresh frozen plasma (FFP) is not supported. There was no evidence to define a threshold fibrinogen level or prothrombin ratio/international normalised ratio (INR) that is associated with significant adverse events (Practice Point).

In maternity patients, underlying causes of coagulopathy should be assessed and treated. Where transfusion of platelets, cryoprecipitate or FFP is considered necessary, the risks and benefits should be considered for each patient, and expert guidance sought (Practice Point).

Maternity patients with pre-existing haematological conditions (e.g., thrombocytopenia, inherited or acquired disorders of coagulation) should have their condition optimised before giving birth, and have a multidisciplinary plan in place for birth and the postnatal period (Practice Point).

Obstetric Haemorrhage/Critical Bleeding

Major blood loss can develop rapidly around the time of giving birth in the absence of haemodynamic compromise; hence, close monitoring of all women, and early recognition and rapid response, are critical (Practice Point).

In maternity patients requiring massive transfusion, the use of RBC and other blood components may be life-saving. However, in nonâ€‘maternity patients, transfusion of RBC and other blood components is independently associated with increased morbidity and mortality (Practice Point).

In maternity patients with critical bleeding, a structured approach to patient care that includes escalation procedures, and timely and appropriate use of RBC and other blood components (e.g., a massive transfusion protocol [MTP]), may reduce the risk of morbidity and mortality (Practice Point).

All providers of birthing services should develop a plan to manage obstetric haemorrhage. The plan should give consideration to local resources, transport and access to relevant specialist advice, blood products and equipment (Practice Point).

In women with major obstetric haemorrhage, in addition to clinical observations, the following parameters should be measured early and frequently:

- Temperature
- Acid–base status

- Ionised calcium
- Haemoglobin
- Platelet count
- Prothrombin time (PT)/INR
- Activated partial thromboplastin time (APTT)
- Fibrinogen level

With successful treatment, values should trend towards normal (Practice Point).

Values indicative of critical physiologic derangement include:

- Temperature <35°C
- pH <7.2, base excess worse than –6, lactate >4 mmol/L
- Ionised calcium <1.1 mmol/L
- Platelet count $<50 \times 10^9$/L
- PT >1.5 × normal
- INR >1.5
- APTT >1.5 × normal
- Fibrinogen level <2.0 g/L

(Practice Point)

In women with major obstetric haemorrhage requiring massive transfusion, suggested doses of blood components are:[a]

- FFP: 15 mL/kg
- Platelets: 1 adult therapeutic dose
- Cryoprecipitate: 3–4 g (Practice Point)

In pregnant women at risk of major obstetric haemorrhage (e.g., women with placenta accreta or major placenta previa), a multidisciplinary management plan is strongly advised (Expert Opinion Point).

[a]Or as directed by the haematologist/transfusion specialist. See Appendix E in the original guideline document for dose equivalents.

Massive Transfusion Protocol for Maternity Care

It is strongly advised that maternity services develop an MTP that includes access to RBC and the dose, timing and ratio of blood component therapy, for use in maternity patients with critical bleeding requiring massive transfusion (Expert Opinion Point).

In the maternity population, activate MTPs early (Expert Opinion Point).

The MTP should be modified for the maternity patient, because fibrinogen levels approaching 2 g/L are indicative of critical physiological derangement and are associated with severe haemorrhage (Expert Opinion Point).

Obstetric Haemorrhage/Critical Bleeding - Transfusion Support for Maternity Services

All maternity services must have procedures in place to manage the critically bleeding maternity patient. This includes agreed communication and transport arrangements, access to transfusion medicine expertise and defined escalation strategies (Expert Opinion Point).

All maternity services should liaise with their local pathology provider to ensure that information on local blood access arrangements is available to all clinicians (e.g., time to process 'group and hold' and cross-match blood, and availability of products) (Expert Opinion Point).

Maternity services in rural and remote areas should develop management plans to minimise any delay in accessing specialist health-care services and resources, including blood products (Expert Opinion Point).

Women with identifiable risk factors for obstetric haemorrhage should, wherever possible, give birth in a maternity service capable of providing the appropriate level of care (Expert Opinion Point).

Recombinant Activated Factor VII (rFVIIa)

The administration of rFVIIa may be considered in maternity patients with life-threatening haemorrhage, but only after conventional measures (including surgical haemostasis and appropriate blood component therapy) have failed[a] (Practice Point). NB: rFVIIa is not licensed for this use. Its

use should only be considered in exceptional circumstances.

Ideally, rFVIIa should only be administered to maternity patients as part of a locally adapted MTP. The MTP should include strict attention to the control of bleeding, physiological and metabolic parameters, coagulation status and temperature maintenance (Practice Point).

When rFVIIa is administered to maternity patients with life-threatening haemorrhage, an initial dose of 90 µg/kg is suggested (Practice Point).

[a]Refer to the NBA guideline Patient blood management guidelines: module 1 - critical bleeding/massive transfusion and the NGC summary of the NBA guideline Patient blood management guidelines: module 2 - perioperative.

Tranexamic Acid (TXA)

In maternity patients with significant blood loss, the early use (within 3 hours of the onset of haemorrhage) of TXA may be considered[a] (Practice Point).

TXA should only be administered in the context of overall patient management; the protocol should include strict attention to the control of bleeding, physiological and metabolic parameters, coagulation status and temperature maintenance (Practice Point).

[a]The use of TXA in this context is considered off label.

Cell Salvage

In maternity patients, cell salvage should be considered if anticipated blood volume loss is likely to result in transfusion[a] (Practice Point).

In maternity patients who are at increased risk of bleeding and in whom transfusion is not an option, cell salvage should be considered (Practice Point).

Cell salvage requires a local procedural guideline that should include patient selection, use of equipment and reinfusion. All staff operating cell salvage devices should receive appropriate training, to ensure that they are familiar with and proficient in the technique (Practice Point).

In Rh D negative maternity patients receiving salvaged blood where the cord blood group is Rh D positive, a dose of Rh D immunoglobulin is required, with additional doses based on the result of assessment of fetomaternal haemorrhage test (Practice Point).

[a]In accordance with Guidance for the provision of intraoperative cell salvage.

Interventional Radiology (IR)

Preventative IR may be appropriate in selected maternity patients; however, the risk of complications from this procedure should be balanced against the potential benefits (Practice Point).

Although the role of therapeutic IR in the treatment of major obstetric haemorrhage is unknown, it may be considered in the overall approach to management (Practice Point).

Definitions

National Health and Medical Research Council (NHMRC) Evidence Hierarchy: Designations of Levels of Evidence According to Type of Research Question*

Level	Intervention[a]	Prognosis	Aetiology[b]
I[c]	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A prospective cohort study[d]	A prospective cohort study
III-1	A pseudo randomised controlled trial (i.e., alternate allocation or some other method)	All or none[e]	All or none[e]
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial[f] • Cohort study • Case–control study • Interrupted time series with a control	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study

Level	group Intervention[a]	Prognosis	Aetiology[b]
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study[g] • Interrupted time series without a parallel control group	A retrospective cohort study	A case–control study
IV	Case series with either post-test or pre-test/post-test outcomes	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series

*Source: National Health and Medical Research Council (NHMRC) (2009). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. NHMRC. https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

[a]Definitions of these study designs are provided on pages 7-8, *How to use the evidence: assessment and application of scientific evidence* (NHMRC, 2000).

[b]If it is possible and ethical to determine a causal relationship using experimental evidence, then the 'intervention' hierarchy of evidence should be utilised. If it is only possible or ethical to determine a causal relationship using observational evidence (e.g., groups cannot be allocated to a potential harmful exposure, such as nuclear radiation), then the 'aetiology' hierarchy of evidence should be utilised.

[c]A systematic review will only be assigned a level of evidence as high as the studies it contains, except where those studies contain Level II evidence. Systematic reviews of Level II evidence provide more data than the individual studies, and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome or result, as different studies (and study designs) might contribute to each different outcome.

[d]At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[e]All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

[f]This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C).

[g]Comparing single arm studies, i.e., case series from two studies. This would also include unadjusted indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C, without statistical adjustment for B).

Body of Evidence Matrix

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence Base	Several Level I or II studies with low risk of bias	One or two Level II studies with low risk of bias or a systematic review, or multiple Level III studies with low risk of bias	Level III studies with low risk of bias, or Level I or II studies with moderate risk of bias	Level IV studies, or Level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency can be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in the body of evidence are different to the target population but it is clinically sensible to apply this evidence to the target population for the guidelines	Population/s studied in the body of evidence are different to the target population, and it is hard to judge whether it is sensible to generalise to the target population for the guidelines
Applicability	Directly applicable to the Australian healthcare	Applicable to Australian healthcare context, with a few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to the Australian healthcare context

Component	context A	B	C	D
	Excellent	Good	Satisfactory	Poor

Grade of Recommendation

Grade A: Body of evidence can be trusted to guide practice.

Grade B: Body of evidence can be trusted to guide practice in most situations.

Grade C: Body of evidence provides some support for recommendation(s) but care should be taken in its application.

Grade D: Body of evidence is weak and recommendations must be applied with caution.

Practice Point: The systematic review found insufficient high-quality data to produce evidence-based recommendations, but the CRG felt that clinicians require guidance to ensure good clinical practice.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Obstetric and postpartum haemorrhage
- Anaemia during pregnancy and the postpartum period

Guideline Category

Evaluation

Management

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Hematology

Internal Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Hospitals

Physician Assistants

Physicians

Guideline Objective(s)

To assist and guide health-care professionals in making clinical decisions when managing pregnant and postpartum women

Target Population

Pregnant and postpartum (within 6 weeks of the end of pregnancy) women

Note: All the recommendations, practice points and expert opinion points contained in this guideline also apply to Aboriginal and Torres Strait Islander women.

Interventions and Practices Considered

1. Oral and/or parenteral iron supplementation
2. Erythropoiesis-stimulating agents (ESAs)
3. Blood group and antibody testing during pregnancy, with follow-up testing for Rh D negative women and women with alloantibodies capable of causing haemolytic disease of the newborn
4. Ferritin testing in women at high risk of anaemia
5. Screening for deficiencies in folic acid and vitamin B12
6. Screening for hookworm
7. Provision of advice on minimising anaemia
8. Procedures to minimise blood loss when transfusion is not an option (e.g., hysterectomy)
9. Red blood cell transfusion
10. Evaluation of haemoglobin concentration and clinical assessment to guide transfusion
11. Use of cytomegalovirus (CMV) seronegative and phenotyped blood components
12. Transfusion of platelets, cryoprecipitate or fresh frozen plasma (FFP)
13. Monitoring of women with obstetric haemorrhage/critical bleeding: temperature, acid–base status, ionised calcium, haemoglobin, platelet count, prothrombin time (PT)/international normalised ratio (INR), activated partial thromboplastin time (APTT), fibrinogen level
14. Development of a massive transfusion protocol for maternity care
15. Development of transfusion support for maternity services
16. Use of recombinant activated factor VII (rFVIIa)
17. Tranexamic acid (TKA)
18. Cell salvage
19. Preventative and therapeutic interventional radiology

Major Outcomes Considered

- Maternal and perinatal mortality
- Functional and performance status (postnatal depression, breastfeeding rates)
- Measures of fetal outcome (birthweight, gestation, preterm delivery)
- Transfusion-related serious adverse serious adverse events (transfusion-related circulatory volume overload [TACO], transfusion-related acute lung injury [TRALI], other including infection)
- Thromboembolic events (stroke, myocardial infarction, deep vein thrombosis, pulmonary embolism)
- Transfusion dose/volume (in transfused patients only) or transfusion incidence
- Laboratory measures: haemoglobin (Hb), haematocrit (Hct), ferritin, international normalised ratio (INR), prothrombin time/activated partial thromboplastin time (APTT), platelet count, fibrinogen level
- Additional interventions to control bleeding (only: hysterectomy, compression sutures, uterine packing [forms of], uterine artery ligation, radiological embolisation) - *bleeding patients only*

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Clinical Research Questions

Question Development Summary

Between July 2010 and March 2011, the relevant clinical research questions for this module were developed, prioritised, combined and refined by the Expert Working Group (EWG), the independent systematic review expert and the Clinical/Consumer Reference Group (CRG). The process is described in greater detail in the technical reports accompanying these guidelines (see the "Availability of Companion Documents" field). The clinical research questions for systematic review were all intervention questions structured according to PICO (population, intervention, comparator and outcome) criteria. Three main strategies were used to identify potentially relevant literature: electronic database searching, manual searching and use of literature recommended by expert members of the CRG. The primary databases searched were EMBASE, Medline, the Cochrane Library Database and PreMedline. Additional searches were conducted on Health Technology Assessment and guideline Web sites (e.g., National Institute for Health and Care Excellence [NICE], Canadian Agency for Drugs and Technologies in Health [CADTH]) and clinical trial registries.

Background Material

Material relevant to background questions was gathered by consultants or registrars under the supervision of CRG members. Sources included medical textbooks, grey literature, published scientific and review articles, series yearbooks and other relevant medical literature; however, systematic review processes were not applied. The questions researched are listed in Box 2.2 in the original guideline document.

Review and Research

Systematic Review Process

Systematic reviews were undertaken to attempt to answer the single question specific to patient blood management (PBM) in a maternity setting, and the three generic questions considered relevant to this module.

To answer these questions (see Box 2.1 in the original guideline document), comprehensive search strategies were designed, as detailed in Technical Report Volume 2 (see the "Availability of Companion Documents" field). Searches were conducted in relevant electronic databases, bibliographies of studies identified as relevant and literature recommended by expert members of the CRG. The search terms did not specifically search for or limit retrieval of articles to studies that addressed socioeconomic, Aboriginal or Torres Strait Islander subgroups. However, the reviewers were required to isolate any papers addressing these populations for specific consideration by the CRG. No papers were identified that addressed these populations specifically. However, implications for rural and remote areas, and the Indigenous population, have been considered and documented in the clinical guidance.

Literature Search Dates

The systematic reviews for this module included only data from studies that met the relevant inclusion criteria, were of adequate quality and were published before 12 June 2013. Identification of relevant evidence and assessment of evidence was conducted in accordance with the *Procedures and requirements for meeting the 2011 standard for clinical practice guidelines*.

Inclusion and Exclusion Criteria

The questions included in this module were crafted in such a way that they attempted to provide answers in clinically relevant areas of uncertainty. They were further refined through consultation among the systematic reviewer, CRG, National Blood Authority (NBA) and the independent systematic review expert. Details of research question criteria are presented in Technical Report Volume 1 (see the "Availability of Companion Documents" field).

Briefly, inclusion criteria were determined from the PICO criteria that formed the basis of the systematically reviewed research questions. Non-English publications were excluded.

Number of Source Documents

See Appendix C in Technical Report Volume 2 for tables depicting literature search results and included studies for all review questions (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

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[d]At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[e]All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

[f]This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C).

[g]Comparing single arm studies, i.e., case series from two studies. This would also include unadjusted indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C, without statistical adjustment for B).

Body of Evidence Matrix

Component	A	B	C	D
	Excellent	**Good**	**Satisfactory**	**Poor**
Evidence Base	Several Level I or II studies with low risk of bias	One or two Level II studies with low risk of bias or a systematic review, or multiple Level III studies with low risk of bias	Level III studies with low risk of bias, or Level I or II studies with moderate risk of bias	Level IV studies, or Level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency can be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted
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Applicability	Directly applicable to the Australian healthcare context	Applicable to Australian healthcare context, with a few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to the Australian healthcare context

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Systematic reviews were undertaken to attempt to answer the single question specific to patient blood management (PBM) in a maternity setting, and the three generic questions considered relevant to this module. The systematic review questions are listed in Box 2.1 in the original guideline document. Refer to the Technical Reports (see the "Availability of Companion Documents" field) for details concerning the systematic review process and all evidence summary tables.

Classification and Assessment of Evidence

Studies identified for inclusion from the literature search were classified according to the National Health and Medical Research Council (NHMRC) levels of evidence hierarchy (see the "Rating Scheme for the Strength of the Evidence" field). To ensure that modules were based on the best available evidence, studies of higher levels of evidence (Levels I or II) were included in preference to those presenting lower levels of evidence (Levels III or IV). This was to minimise the potential for bias in the evidence base for each systematically reviewed question. However, lower level studies were reviewed where evidence was not available in higher level studies for any of the primary outcomes.

Studies identified from the systematic literature review were assessed according to NHMRC dimensions of evidence (see Table 2.2 in Technical Report Volume 1). There are three main domains: strength of the evidence, size of the effect, and relevance of the evidence. The first domain was derived directly from the literature identified for a particular intervention, aetiology or prognostic study. The other two domains were determined in consultation with the Clinical/Consumer Reference Group (CRG) as part of the study assessment process during the review of the evidence considered for module development. An aspect of the strength of the evidence domain is the level of evidence of the study, which was determined as described above using the NHMRC levels of evidence hierarchy.

Quality Appraisal

The methodological quality of the included studies was assessed using the criteria presented in Appendix 2 of Technical Report Volume 1 (see the "Availability of Companion Documents" field). Quality assessment criteria varied according to whether included studies were systematic reviews, randomised controlled trials (RCTs), cohort studies or case–control studies. No weighting of quality criteria was applied, but studies that met all criteria, or all but one, were considered good quality with a low risk of bias. Quality assessments of included studies for all systematically reviewed research questions are presented in Appendix E of Technical Report Volume 2.

Data Extraction

Data and information were extracted into evidence summary tables according to the inclusion criteria. Evidence summary tables were based on NHMRC requirements for externally developed guidelines. All articles retrieved for full text review were initially screened, critically appraised, and data extracted by one evidence reviewer. A second reviewer independently checked and reviewed all articles, data extractions, and quality assessments. Any disagreements were resolved by a third reviewer.

Extracted data and information included general study details (citation, study design, evidence level, country and setting), characteristics of study participants, details of interventions and comparators, details of internal (e.g., allocation and blinding) and external (applicability and generalisability) study validity, and results for outcomes specified in the inclusion criteria. Where relevant studies were identified, extracted data and information were used to construct study characteristics and results tables of included evidence for each systematically reviewed research question. Evidence summary tables for all included studies are presented in Appendix F of Technical Report Volume 2.

Assessment of the Body of Evidence

The body of evidence for each module recommendation was graded in accordance with the NHMRC framework for developing evidence-based recommendations. Assessment of the body of evidence considers the dimensions of evidence of studies relevant to that recommendation. A modified NHMRC evidence statement form was used with each clinical research question considered in the development of the guidelines (see Appendix 3 of Technical Report Volume 1). That is, a separate form was used for consolidation of the evidence (evidence statement form) and the development of recommendations (recommendation form). The decision to separate out the two components of the NHMRC evidence statement form was due to the inevitability of several evidence statement forms leading to only one recommendation. Also, the current NHMRC evidence statement form does not provide a space to capture the actual wording of evidence statements.

Before the evidence statement form was completed, included studies were critically appraised and relevant data were summarised, as described. This information was required to formulate each recommendation and determine the overall grade of the body of evidence supporting each recommendation.

The key findings from included studies were summarised as evidence statements for each systematically reviewed research question. Where required, separate evidence statements were developed for different patient populations and outcomes. CRG input helped ensure that the size of effects and relevance of evidence were considered when developing evidence statements. Where no evidence or insufficient relevant evidence was identified, this was explained in the evidence statement.

Refer to Technical Report Volume 1 for Steps 1 and 2 in using the NHMRC evidence statement form. Completed evidence statement forms and recommendations for each research question are presented in Appendix D of Technical Report Volume 2.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Clinical/Consumer Reference Group (CRG) developed recommendations where sufficient evidence was available from the systematic review

of the literature. The recommendations have been carefully worded to reflect the strength of the body of evidence. Each recommendation has been given a grade, which were set by the National Health and Medical Research Council (NHMRC) (see section 2 in the original guideline document for further information on this process).

Governance Structure

A multilevel management framework was established by the National Blood Authority (NBA) to coordinate the development of the new patient blood management (PBM) guidelines. The management framework consists of:

- A Steering Committee, which was responsible for the initial development and governance of the entire project; this has now become the PBM Steering Committee, which oversees the implementation strategy for the PBM Guidelines
- An Expert Working Group (EWG), responsible for providing advice on scope, clinical oversight and integration of the six modules
- CRGs – one for each of the six modules, with membership including representation from relevant colleges, societies and consumer groups, to provide expert knowledge and input
- Systematic reviewers and a technical writer, contracted by the NBA to review the literature and develop a draft of each module
- An independent systematic review expert, to provide advice and mentoring to the systematic reviewers, technical writer and CRGs; and to ensure that the development process and the guidelines produced comply with NHMRC requirements

The NBA provided the secretariat, project funding and project management. Appendix A3 in the original guideline document lists the membership of the bodies involved in governance of the guidelines. Details of how the guidelines will be implemented and updated are provided in Chapter 6 of the guideline. Figure A1 in the original guideline document illustrates the management framework used to manage the development of the six modules of the guidelines.

Formulation of Recommendations

Use of the NHMRC Evidence Statement Form

Step 3: Formulation of a Recommendation Based on the Body of Evidence

Step 3 involved formulating the wording of the recommendation. This wording was intended to reflect the strength of the body evidence; that is, where the evidence base was regarded as poor or unreliable, words such as 'must' or 'should' were not used. The wording of recommendations was developed in conjunction with the CRG during meetings to review the evidence base for research questions.

Step 4: Determination of the Grade for the Recommendation

The overall grade for each recommendation was determined from a summary of the rating for each component of the body of evidence (outlined in the "Rating Scheme for the Strength of the Evidence" field). Definitions of the NHMRC grades of recommendations are presented in the "Rating Scheme for the Strength of the Recommendations" field. In accordance with the NHMRC framework, recommendations were not graded A or B unless the evidence base and consistency of evidence were both rated A or B unless only one study was included and consistency was rated 'N/A'. In this situation the quality, size and strength of the evidence base was relied upon to grade the recommendation. The grading of recommendations was determined in conjunction with the CRG.

Developed recommendations were entered into the recommendation forms, and the corresponding evidence statement forms were noted, along with the overall grade determined in this step (see Appendix D of Technical Report Volume 2 [see the "Availability of Companion Documents" field]).

Practice Points

Practice points were developed by the CRG through a facilitated group discussion and consensus process (see Appendix 4 in Technical Report Volume 1 [see the "Availability of Companion Documents" field]) in the following circumstances:

- Where the underpinning evidence would have led to a grade D evidence-based recommendation
- Where the CRG developed evidence-based recommendations graded C and above, but considered that additional information was required to guide clinical practice (wherever possible, this guidance was sourced from other evidence-based guidelines assessed to be of high quality)
- Where insufficient evidence was identified to support the development of an evidence-based recommendation

Refer to Section B4 in the original guideline document for information on development of expert opinion points.

Rating Scheme for the Strength of the Recommendations

Grade of Recommendation

Grade A: Body of evidence can be trusted to guide practice.

Grade B: Body of evidence can be trusted to guide practice in most situations.

Grade C: Body of evidence provides some support for recommendation(s) but care should be taken in its application.

Grade D: Body of evidence is weak and recommendations must be applied with caution.

Practice Point: The systematic review found insufficient high-quality data to produce evidence-based recommendations, but the Clinical/Consumer Reference Group (CRG) felt that clinicians require guidance to ensure good clinical practice.

Cost Analysis

A specific literature search for economic evidence was not conducted. It was intended that the technical report would incorporate an appraisal of any relevant economic evidence if identified in the literature searches; however, no such evidence was found.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Public Consultation

Public consultation was conducted for six weeks from Monday 16th June to Friday 25th July, 2014, during which time the draft module was available on the National Blood Authority (NBA) Web site. Notification was posted in *The Australian* national newspaper, and the NBA invited a range of stakeholders, committees, working groups and interested people to provide submissions via email. A full list is detailed in the public consultation submissions report.

A formal letter advising of public consultation was sent to the organisations with a representative on the Clinical/Consumer Reference Group (CRG). An email was sent to the following:

- Members of each of the previous and current Expert Working Group (EWG), CRGs and patient blood management (PBM) Steering Committee
- Relevant colleges, societies and other health organisations
- Individuals registered to receive PBM Guideline updates
- Therapeutic Goods Administration (TGA)
- Director General/Chief Executive/Secretary of each state, territory and health department
- Pharmaceutical Benefits Advisory Committee
- Medical Services Advisory Committee
- Australian Red Cross Blood Service
- Consumers Health Forum of Australia and the major consumer organisation in each state and territory

Twenty-one submissions were received. The CRG met in August 2014 to consider all the public consultation submissions and, where necessary, revise this module in accordance with the submissions. Changes were made to the module to address comments and concerns raised in submissions, and to improve clarity.

Finalising the Guidelines

Appraisal of Guidelines for Research and Evaluation (AGREE) II Assessment

The AGREE II instrument was developed to address the issue of variability in guideline quality and assesses the methodological rigour and transparency in which a guideline is developed. The post-public consultation version of the module was sent to two Australian reviewers,

independent to the guideline development process, who used the AGREE II tool to assess the quality and usability of the module against international quality standards.

Both AGREE II assessors would recommend the guideline for use, and gave a rating of six out of seven for its overall quality (with seven being the highest possible quality rating).

Additional Review

The final drafts of the module and technical reports were reviewed by a guidelines development expert (formerly a Guidelines Assessment Register consultant) to assess compliance with National Health and Medical Research Council (NHMRC) requirements for externally developed guidelines. The module and accompanying documents were then sent to the NHMRC for methodological and independent peer review on 26 September 2014.

NHMRC Approval

Approval from the Council was received on 22 December 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improvement of clinical outcomes by avoiding unnecessary exposure to blood components including:

- Optimisation of blood volume and red cell mass
- Minimisation of blood loss
- Optimisation of the patient's tolerance of anaemia

Patient blood management (PBM) improves patient outcomes by ensuring that the focus of the patient's medical and surgical management is on improving and conserving the patient's own blood. As a consequence of the better management, patients usually require fewer transfusions of donated blood components, thus avoiding transfusion-associated complications.

Potential Harms

Traditionally, it has been assumed that blood transfusion benefits patients; however, a benefit has not been demonstrable in many clinical scenarios. In addition, evidence is accumulating that serious nonâ€‘viral adverse events, such as transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI), are more common than previously thought, and that more recently identified conditions (e.g., transfusion-related immunomodulation) may cause patients harm.

The risk of transmission of infectious diseases through blood transfusion has reduced significantly in recent years, through improved manufacturing and laboratory processes. However, there is potential for transfusion of an unrecognised infectious agent.

Despite improvements in systems management, there remains a risk of transfusion-related harm due to administrative error. Such an error has the potential to result in acute haemolytic reaction from ABO incompatibility, which may be fatal.

If the patient requires therapy for anaemia, thrombocytopaenia or coagulopathy, transfusion should not be a default decision. Instead, the decision on whether to transfuse should be carefully considered, and should:

- Take into account the full range of available therapies

- Balance the evidence for efficacy and improved clinical outcome against the risks
- Take into account patient values and choices

Table C.1 in the original guideline document summarises transfusion risks, and Table C.2 presents the Calman Chart (United Kingdom risk per one year), which may be useful to clinicians for explaining risks to patients.

Recombinant erythropoiesis stimulating agents (ESAs) promote bone marrow production of red blood cells (RBCs); however, ESA use is associated with complications of therapy, particularly where the baseline haemoglobin (Hb) is near normal. Accordingly, the effectiveness of ESAs in treating anaemia must be balanced against these risks.

Interventional radiology (IR) techniques may be less efficacious in maternity patients than in other groups because of the extensive collateral pelvic circulation in the former. Also, they require access to imaging technology and an experienced interventional radiologist. Potential safety concerns include fetal exposure to radiation if catheterisation occurs before birth, and direct complications of arterial thrombosis and dissection.

Contraindications

Contraindications

'Permitted hypotension' may be a contraindication in management of obstetric haemorrhage if the uterus is still in situ and the aim is to optimise the chance for the uterus to contract (and respond to medical management).

Qualifying Statements

Qualifying Statements

- This document is a general guide to appropriate practice, to be followed subject to the circumstances, clinician's judgement and patient's preferences in each individual case. It is designed to provide information to assist decision making. Recommendations contained herein are based on the best available evidence published up to 12 June 2013. The relevance and appropriateness of the information and recommendations in this document depend on the individual circumstances. Moreover, the recommendations and guidelines are subject to change over time.
- Each of the parties involved in developing this document expressly disclaims and accepts no responsibility for any undesirable consequences arising from relying on the information or recommendations contained herein.
- This publication reflects the views of the authors and not necessarily the views of the Australian Government.
- If the patient requires therapy for anaemia, thrombocytopaenia or coagulopathy, transfusion should not be a default decision. Instead, the decision on whether to transfuse should be carefully considered, and should:
    - Take into account the full range of available therapies
    - Balance the evidence for efficacy and improved clinical outcome against the risks
    - Take into account patient values and choices
- In the process of obtaining informed consent, a clinician should allow the patient sufficient time to ask questions, and should answer those questions. If the patient is unable to speak or understand English, the clinician may need to involve an interpreter. In certain contexts, a trained medical interpreter may be required (rather than a family member or a friend). Written information and diagrams may be appropriate in certain circumstances to aid understanding.
- All elements of the consent process should reflect local, state, territory or national requirements.

Implementation of the Guideline

Description of Implementation Strategy

Implementing, Evaluating and Maintaining the Guidelines

The National Blood Authority (NBA), in collaboration with the Steering Committee, developed a plan to guide appropriate communication on the implementation of this module. The plan identifies target audiences for the module, strategies and tools for effective implementation, communication channels and key messages.

Continued re-evaluation of the guidelines is necessary to reduce variation in practice patterns, support appropriate use of blood component therapy and reduce inappropriate exposure of patients to blood components. A plan was designed to evaluate implementation of the six modules of the guidelines and to determine:

- The extent to which the guidelines influence changes in clinical practice and health outcomes
- What factors (if any) contribute to non-compliance with the guidelines

The results of the evaluation will be used to inform future development and review of the guidelines. Economic issues were considered when formulating the evidence-based recommendations, and these recommendations will have cost implications. The NBA, together with the Jurisdictional Blood Committee (JBC) and key stakeholders, developed the *National Patient Blood Management Guidelines Implementation Strategy 2013–17* to facilitate uptake of the guidelines.

The implementation strategy includes the development of tools to support the introduction of patient blood management (PBM) practices in the clinical setting. The tools are being developed with the help of a network of clinicians with an interest in PBM. The NBA has also funded the development of online courses within the BloodSafe eLearning Australia Program (e.g., iron deficiency anaemia, PBM, Critical Bleeding and Perioperative). In addition, the NBA, in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC), has developed a hospital guide to support the implementation of the *National Safety and Quality Health Service Standards*. The guide provides links to the PBM guidelines and tools, and the BloodSafe eLearning Australia courses. These resources provide tools to support uptake of the recommendations in this module.

Implementation of Guidelines Recommendations

The National Health and Medical Research Council (NHMRC) framework directs that guidelines implementation should be considered at the same time as recommendations are formulated. The recommendation form contains questions related to the implementation of each module (see Appendix 4 in Technical Report Volume 2 [see the "Availability of Companion Documents" field]). These are:

- Will this recommendation result in changes in usual care?
- Are there any resource implications associated with implementing this recommendation?
- Will the implementation of this recommendation require changes in the way care is currently organised?
- Is the guidelines development group aware of any barriers to the implementation of this recommendation?

This section of the recommendation form was completed in consultation with the Clinical/Consumer Reference Group (CRG) when each recommendation was formulated and graded. Implementation issues are recorded in the recommendation forms presented in Appendix D of Technical Report Volume 2 (see the "Availability of Companion Documents" field).

Implementation Tools

Audit Criteria/Indicators

Mobile Device Resources

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

National Blood Authority. Patient blood management guidelines: module 5 - obstetrics and maternity. Canberra ACT (Australia): National Blood Authority; 2015. 129 p. [134 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015

Guideline Developer(s)

National Blood Authority - National Government Agency [Non-U.S.]

Source(s) of Funding

Funding, secretariat and project management was provided by the National Blood Authority Australia. The development of the final recommendations has not been influenced by the views or interests of the funding body.

Guideline Committee

Steering Committee

Expert Working Group

Clinical/Consumer Reference Group (CRG) - Obstetrics and Maternity

Composition of Group That Authored the Guideline

Steering Committee: Dr Lilon Bandler, General Practice and community medicine; Ms Karen Carey, Consumers Health Forum; Dr Steve Flecknoe-Brown, Haematology; Ms Trudi Gallagher, Jurisdictional PBM coordinator/Clinical Nurse Consultant; Prof James Isbister, Clinical Academic Expert; Ms Kathy Meleady, Australian Commission on Quality and Safety in Healthcare; Dr Beverley Rowbotham, Private pathology; Dr Ben Saxon, Australian Red Cross Blood Service; Dr Amanda Thomson, Australian & New Zealand Society of Blood Transfusion; Prof Simon Towler, Patient Blood Management Expert and Chair

Expert Working Group: A/Prof Mark Dean, Royal Australasian College of Physicians and Haematology Society of Australia & New Zealand; A/Prof Craig French, Australian and New Zealand Intensive Care Society and College of Intensive Care Medicine of Australia and New Zealand; A/Prof Helen Liley, Royal Australasian College of Physicians (Paediatrics and Child Health Division) and Perinatal Society of Australia and New Zealand; A/Prof Larry McNicol, Australian and New Zealand College of Anaesthetists; Dr Helen Savoia, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; Dr Amanda Thomson, Australian & New Zealand Society of Blood Transfusion

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Financial Disclosures/Conflicts of Interest

All members of the Steering Committee, Clinical/Consumer Reference Group (CRG), Expert Working Group (EWG) and systematic review team declared any interests before starting work on the guidelines. Declarations were also reviewed at intervals, as new declarations were required to be declared to the Chair prior to the start of each meeting as a standing agenda item on each day of a meeting. The National Blood Authority (NBA) keeps a register of all declared interests. If an interest is declared, and the Chair decides it should be considered by the CRG, the CRG decides by consensus whether it affects the proceedings. If the interest is considered to be competing or in conflict, the Chair can prevent the member from participating in discussions and decisions pertaining to the declared interest.

See Appendix B in the original guideline document for declarations made during the guideline development process.

The Chair considered these declarations and determined that they did not constitute a conflict. Members were not asked to leave the room at any time during their involvement in the guideline development process. None of the NBA and Optum staff had any declarations.

Guideline Endorser(s)

Australian and New Zealand College of Anaesthetists - Medical Specialty Society

Australian College of Rural and Remote Medicine - Professional Association

Australian Red Cross Blood Service - Nonprofit Organization

College of Intensive Care Medicine of Australia and New Zealand - Medical Specialty Society

Perinatal Society of Australia and New Zealand - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the National Blood Authority (NBA) Web site.

Availability of Companion Documents

The following are available:

- Patient blood management guidelines: module 5 - obstetrics and maternity. Quick reference guide. Canberra ACT (Australia): National Blood Authority; 2015. 16 p. Available from the National Blood Authority (NBA) Web site.
- Patient blood management guidelines: module 5 - obstetrics and maternity. Technical report. Volume 1. Review of the evidence. Canberra ACT (Australia): National Blood Authority; 2015 Feb. 213 p. from the NBA Web site.
- Patient blood management guidelines: module 5 - obstetrics and maternity. Technical report. Volume 2. Appendixes. Canberra ACT (Australia): National Blood Authority; 2015 Feb. 343 p. Available from the NBA Web site.

A variety of additional implementation resources, including audit tools, templates, case studies, and other guidance, are available from the NBA Web site. Instructions on how to add the guidelines to your mobile device are available from the NBA Web site.

Patient Resources

Various tools and resources to support patients in patient blood management decision making are available on the National Blood Authority (NBA) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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